IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy Products Liability Litigation	)	**Case No. 14 C 1748**
	)	**MDL No. 2545**
(This document applies to *Loreto v. AbbVie Inc.*, Case No. 16 C 2561)	)	

CASE MANAGEMENT ORDER NO. 193
(Order on AbbVie's motion for summary judgment and motion to exclude testimony of Dr. Joshua Sharlin and Dr. Hossein Ardehali in *Loreto v. AbbVie Inc.*, No. 16 C 2561)

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation (MDL) proceeding allege that they suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins (venous thromboembolisms) as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendants AbbVie Inc., AbbVie Products LLC, Abbott Laboratories, Inc., and Unimed Pharmaceuticals, Inc (collectively, AbbVie) manufacture AndroGel, one of the TRT products at issue in this litigation. Michael Loreto alleges that his use of AndroGel caused him to suffer a heart attack in February 2014. He asserts claims against AbbVie for strict liability, negligence, breach of warranty, fraud, consumer protection, and punitive damages, as well as other claims. His wife, plaintiff Patricia Loreto, has also asserted a claim for loss of consortium.

AbbVie has moved for summary judgment on all of Loreto's claims. For the following reasons, the Court grants AbbVie's motion for summary judgment on the negligence, implied warranty, fraud, negligent misrepresentation, unjust enrichment,

consumer protection, and punitive damages claims but otherwise denies the motion.

Background

A. Factual background

The Court assumes familiarity with the background as set out in its prior case management orders and therefore discusses only those details uniquely relevant to the plaintiffs' claims. The Court recounts the following facts from the parties' Local Rule 56.1 statements, exhibits, and summary judgment briefing. The facts are undisputed except where otherwise stated.

Loreto is a citizen of New Jersey. He began using AndroGel in March 2012 after his family physician, Dr. James Agresti, II, prescribed it to treat low libido. Loreto saw Dr. Agresti, II regularly from 1984 until 2013, when he began seeing Dr. James Agresti, III. During his April 2021 deposition, Loreto testified that he has seen Dr. Agresti, III for annual physical checkups since 2013. He also stated that he used AndroGel daily from March 2012 until February 2014.

On January 31, 2014, the Food and Drug Administration (FDA) issued a "Safety Announcement" stating that it was investigating the risk of cardiovascular injury in men using TRT products like AndroGel. Less than a month later, on February 26, 2014, Loreto suffered a heart attack. Loreto stopped using AndroGel after his heart attack and brought this suit in February 2016 in the District of New Jersey.

B. Experts

In support of his case, Loreto offers the reports and testimony of two experts: Dr. Joshua Sharlin and Dr. Hossein Ardehali.

Dr. Sharlin, Loreto's regulatory expert, states in his report that he believes

AbbVie should have warned Loreto or his doctors of the cardiovascular risks of AndroGel before Loreto's 2014 injury. Dr. Sharlin testified that he relied on Dr. Ardehali's medical conclusions on causation in making his regulatory conclusions. Dr. Sharlin also testified that he believes AbbVie failed to properly analyze the adverse events in the FDA's Adverse Event Reporting System (FAERS).

FAERS contains all the reports on adverse events—such as heart attacks—that the FDA receives concerning various medications, including TRT drugs like AndroGel. Dr. Sharlin stated that he believed AbbVie's safety analysis undercounted the number of heart attack-related adverse event reports because it only investigated AndroGel-related adverse events reports in FAERS, whereas Dr. Sharlin's analysis also accounted for adverse event reports associated with other TRT drugs. During his deposition, Dr. Sharlin admitted that FAERS contains duplicate reports and underreports the total number of adverse events, and he stated that he did not check whether the data he used contained any duplicates. He also testified that confirming his data would require AbbVie or a third party to examine the "Primary ID" numbers of the adverse event reports he analyzed, but he did not list those ID numbers in his report.

Dr. Ardehali, Loreto's causation expert, states in his reports that he believes Loreto would not have suffered a heart attack if he had not taken AndroGel. Dr. Ardehali submitted a general report in the MDL in October 2016 and prepared a case-specific report regarding Loreto in February 2021. In November 2021 the Court ordered Loreto to submit any supplemental expert reports by March 25, 2022. In January 2022 the Court ordered the parties in this case and a few others that remained pending to participate in mediation. After the mediation process concluded in June 2022, the Court

extended the deadline for completing non-duplicative fact and expert discovery to August 17, 2022. Loreto did not submit any supplemental reports before March 25, 2022, but he served three supplemental reports prepared by Dr. Ardehali on AbbVie on August 17—one day before Dr. Ardehali's deposition on August 18. Two of the supplemental reports are nearly identical to reports that were previously served on AbbVie in other litigation, and the third supplemental report is specific to Loreto's medical condition.

Discussion

In multidistrict litigation, procedural matters are governed by the law of the transferee jurisdiction, in this case the Seventh Circuit. *See, e.g.*, *In re Pradaxa (Dabigatran Etexilate Prods. Liab. Litig.)*, No. 3:12-md-02385-DRH-SCW, 2013 WL 656822, at *2 (S.D. Ill. Feb 22, 2013); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 889 F. Supp. 2d 931, 936 n.7 (E.D. Ky. 2012); *Various Plaintiffs v. Various Defendants (Oil Field Cases)*, 673 F. Supp. 2d 358, 362 (E.D. Pa. 2009). A party is entitled to summary judgment if it shows that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). There is a genuine issue of material fact, and summary judgment is precluded, "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In ruling on a motion for summary judgment, a court examines the record in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. *Id.* at 255; *see also Parker v. Four Seasons Hotels, Ltd.*, 845 F.3d 807, 812 (7th Cir. 2017).

A. Failure to warn

The parties agree that substantively, New Jersey law governs most of Loreto's claims. New Jersey's Product Liability Act (PLA) "imposes strict liability if a product manufacturer or seller has failed to provide adequate warnings concerning the dangers posed by a product's use." *Hrymoc v. Ethicon, Inc.*, 467 N.J. Super. 42, 84, 249 A.3d 191, 217 (App. Div. 2021) (citing New Jersey Stat. Ann. § 2A:58C-2(b)). Because New Jersey has adopted the learned intermediary doctrine, "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." *Perez v. Wyeth Labs. Inc.*, 161 N.J. 1, 10, 734 A.2d 1245, 1250 (1999) (quoting *Niemiera by Niemiera v. Schneider*, 114 N.J. 550, 559, 555 A.2d 1112, 1117 (1989)).

"A plaintiff must prove that the lack of a warning was a proximate cause of the harm," and "[i]t suffices if the proximate cause is a 'substantial contributing factor to the harm suffered.'" *Hrymoc*, 467 N.J. Super. at 85, 249 A.3d at 217 (citing *Perez*, 161 N.J. at 27, 734 A.2d at 1261). The New Jersey Supreme Court has recognized, however, that "in a failure to warn case, establishing that the absence of a warning was a substantial factor in the alleged harm to have resulted from exposure to the product itself is particularly difficult." *Coffman v. Keene Corp.*, 133 N.J. 581, 600, 628 A.2d 710, 719 (1993) (internal citation and quotation marks omitted). The court in *Coffman* therefore adopted the heeding presumption, agreeing with the Appellate Division's holding that "if a seller or manufacturer is entitled to a presumption that an adequate warning will be read and heeded, plaintiff should be entitled to the *same presumption when no warning is given*." *Id.* at 596, 628 A.2d at 717 (internal citation and quotation

marks omitted) (emphasis added). Once the heeding presumption applies, "the burden of production on the issue of proximate cause shifts to the defendant to come forward with rebuttal evidence." *Sharpe v. Bestop, Inc.*, 314 N.J. Super. 54, 68, 713 A.2d 1079, 1086 (App. Div. 1998). "[I]f [the] defendant presents sufficient evidence to rebut the presumption, . . . the presumption disappears and the plaintiff, consistent with his original burden of persuasion, must prove by a preponderance of the evidence that the failure to warn was a proximate cause of his injury." *Id.* at 67, 713 A.2d at 1086.

In this case, it is undisputed that AbbVie itself did not warn Loreto or either of the Dr. Agrestis of the cardiovascular risks of AndroGel before Loreto's heart attack. Loreto can therefore rely on the heeding presumption to establish causation even though he was not able to depose his prescribing physicians, as "plaintiffs should be entitled to the [] presumption *when no warning is given*" and the presumption is "primarily applicable in circumstances in which plaintiff lacks the ability to prove by direct evidence that a proper warning, if given, would have been heeded." *Coffman*, 133 N.J. at 596, 628 A.2d at 717 (emphasis added); *McDarby v. Merck & Co.*, 401 N.J. Super. 10, 82, 949 A.2d 223, 268 (App. Div. 2008).[1] AbbVie relies largely on a nonprecedential decision to argue otherwise, but that case is inapplicable because it concerned "a pharmaceutical learned

[1] Although AbbVie argues that Loreto could have deposed either of the Dr. Agrestis and chose not to, it does not dispute plaintiffs' counsel's account of both parties' efforts to depose the doctors. Rather, it contends that because Loreto testified that he has seen Dr. Agresti, III regularly for medical purposes since 2013, he did not lack the ability to secure Dr. Agresti, III's testimony or affidavit. But Loreto's deposition occurred in April 2021—before the parties attempted to contact and subpoena either Dr. Agresti—and nothing in the record indicates that either party has been able to contact the doctors since then. Because the Court must draw all reasonable inferences in favor of Loreto as the non-moving party, it declines to infer that Loreto had the ability to provide direct evidence from his prescribing physicians and decided not to do so.

intermediary case *where a manufacturer provided a warning* and its adequacy remains in issue[.]" *In re Accutane(r) Litig.*, No. 271, 2016 WL 5958374, at *11 (Law. Div. Oct. 12, 2016) (emphasis added). Because AbbVie provided no such warning in this case, the heeding presumption applies and "serves to lighten [his] burden of proof concerning proximate causation." *Coffman*, 133 N.J. at 600, 628 A.2d at 719.

AbbVie contends that even if the heeding presumption applies, a court cannot presume that a prescribing physician would *not* have prescribed the drug. That is not the law. When the heeding presumption applies because a drug manufacturer failed to provide a warning, New Jersey courts have presumed that a physician would not have prescribed the drug had there been an adequate warning. *See, e.g.*, *McDarby*, 401 N.J. Super. at 81–82, 949 A.2d at 268 (rejecting defendant's argument that "one cannot 'presume' that additional risk information would lead a prescribing physician to avoid the drug" because "[r]ecognition of that circumstance is incorporated into the generally rebuttable nature of the heeding presumption"); *Baker v. APP Pharms. LLP*, No. 09 C 5725, 2012 WL 3598841, at *8 (D.N.J. Aug. 21, 2012) ("A heeding presumption allows one to presume that the plaintiff's physician would not have prescribed the drug to the plaintiff if there had been an adequate warning; in other words, the plaintiff's physician would have heeded the adequate warning.") (citing *McDarby*, 401 N.J. Super. at 81, 949 A.2d at 267). The Court therefore presumes for purposes of the present case that Loreto's prescribing physician "would have followed an adequate warning had one been provided" and would not have prescribed AndroGel. The burden therefore shifts to AbbVie to rebut the heeding presumption by "produc[ing] evidence that such a warning would not have been heeded." *Coffman*, 133 N.J. at 603, 628 A.2d at 720.

AbbVie has not met this burden via its motion for summary judgment. It cites to no evidence suggesting that either of the Dr. Agrestis would have prescribed AndroGel to Loreto even if AbbVie had warned them of the cardiovascular risks. Instead, AbbVie argues that Loreto must show that he or his physicians had not received the FDA's 2014 safety announcement before his heart attack. Yet the basis of Loreto's claim is that AbbVie—not the FDA—failed to warn of the cardiovascular risks of AndroGel, and AbbVie provides no legal support for its assumption that an FDA statement is equivalent to a warning from a drug manufacturer for purposes of a failure to warn claim.

Had AbbVie shown that either of the Dr. Agrestis had "independent knowledge of the risks" of AndroGel because of the FDA's announcement, then there would be an intervening cause that would preclude Loreto from establishing causation. *Hrymoc*, 467 N.J. Super. at 89, 249 A.3d at 219–20. But nothing in the record suggests that Loreto's prescribing physicians received the announcement or were aware of its contents before Loreto's heart attack, and AbbVie fails to cite any legal authority indicating that a court may assume that physicians are aware of all FDA announcements.[2] Rather, it is "the *manufacturer's burden* to prove an intervening superseding cause or another sole proximate cause of the accident," and any evidence of an intervening cause "must be clear and unequivocal." *Navarro v. George Koch & Sons, Inc.*, 211 N.J. Super. 558,

[2] AbbVie cites to a district court decision that stated "[e]ven an express warning from a drug company, which, of course, was present here, that company will not be liable *if the physician had sufficient knowledge from other sources*." *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1032 (D.N.J. 1988) (emphasis added). AbbVie has not shown however, that Loreto's physicians had any knowledge of the cardiovascular risks of AndroGel from other sources. To the extent that AbbVie is asking the Court to infer that Loreto's doctors knew of the FDA announcement, the Court cannot do so because at this stage it must draw all reasonable inferences in favor of Loreto, the non-moving party.

573, 512 A.2d 507, 515 (App. Div. 1986) (emphasis added); *Hrymoc*, 467 N.J. Super. at 89, 249 A.3d at 219–20. AbbVie has provided no such evidence at all. Because AbbVie is unable to satisfy its burden of proof and rebut the heeding presumption, the Court concludes that a reasonable jury could find that Loreto has established the causation element of his failure to warn claim.

AbbVie also argues that Loreto's failure to warn claim is preempted because it could not have provided a stronger warning, but this argument is unpersuasive. AbbVie contends that the preemption analysis is different in this case because Loreto's injury occurred after the FDA's January 2014 safety announcement, citing to the Court's prior opinion that rejected AbbVie's argument that "communications from the FDA in 2014 further informed doctors about a possible increase in cardiovascular risk" because "each of the bellwether plaintiffs bringing claims based on cardiovascular risk suffered an injury prior to 2014." *In re Testosterone Replacement Therapy Products Liability Litig.*, No. 14 C 1748, MDL No. 2545, 2017 WL 1836435, at *16 (N.D Ill. May 8, 2017) (CMO 47). Yet because AbbVie provides no evidence that Loreto's physicians were aware of the FDA's announcement, the warning that could have been strengthened is not the announcement but AndroGel's label at the time of Loreto's injury. The preemption analysis is therefore no different for Loreto than it was for the earlier bellwether plaintiffs, as AbbVie does not assert that it made changes to AndroGel's label between the bellwether plaintiffs' injuries and Loreto's February 2014 heart attack. The Court has considered and rejected AbbVie's arguments that the bellwether plaintiffs' failure to warn claims were preempted and that AndroGel's label at the time of the bellwether plaintiffs' injuries was adequate as a matter of law. *Id.* at *7–11, *15–16.

Because AbbVie's preemption arguments are all based on the incorrect assumption that it only needed to provide a greater warning than the FDA's announcement, the Court has no reason to revisit its prior ruling on this issue.

Consequently, the Court denies AbbVie's motion for summary judgment on Loreto's failure to warn claim.[3]

B. Design defect

AbbVie also contends that Loreto's design defect claims are preempted, relying on *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015) and a prior decision by this Court in this MDL. *See* CMO 47, 2017 WL 1836435, at *19–21. Although the Court analyzed *Yates* in granting summary judgment on the bellwether plaintiffs' negligent design defect claims, in that same decision the Court also held that strict liability design defect claims are not preempted in states that have adopted comment (k) to section 402(A) of the Restatement (Second) of Torts. *Id.* New Jersey has adopted comment (k). *See Feldman v. Lederle Labs., Inc.*, 97 N.J. 429, 447, 479 A.2d 374, 383 (1984) (“Moreover, even if a prescription drug were unavoidably unsafe, the comment k immunity would not eliminate strict liability for failure to provide a proper warning.”). The Court has previously found that "a genuine dispute exists regarding whether [AbbVie] provided adequate warnings," CMO 47, 2017 WL 1836435, at *19, and AbbVie has presented no basis to conclude otherwise in this case. For this reason, the Court denies AbbVie's motion for summary judgment on Loreto's strict

[3] The parties also dispute whether AbbVie's alleged off-label promotion of AndroGel negates the impact of the FDA's safety announcement. Because AbbVie has failed to produce any evidence showing that Loreto's prescribing physicians were aware of the FDA announcement, the Court need not reach this question for purposes of the motion for summary judgment on the failure to warn claim.

liability design defect claim.

The Court next addresses the negligent design claim. Loreto argues that the Court's rationale for granting judgment on the bellwether plaintiffs' negligent design defect claim does not apply to his case. The Court previously granted summary judgment because it concluded that *Yates* foreclosed any design defect claims based on alternative product designs and the bellwether plaintiffs "cite[d] no case law which supports their contention that they can bring a negligent design defect claim without demonstrating the existence of a feasible alternative design." CMO 47, 2017 WL 1836435, at *20. Loreto contends that New Jersey law does not require proof of a feasible alternative design because it applies a "risk-utility analysis" that "may justify a conclusion that even though no alternative design existed which would have made a product safer, the product is 'so dangerous and of such little use that under the risk-utility analysis [the] manufacturer [should] bear the cost of liability to others.'" *Truchan v. Nissan Motor Corp.*, 316 N.J. Super. 554, 563–64, 720 A.2d 981, 986 (App. Div. 1998) (*quoting Smith v. Keller Ladder Co.*, 275 N.J. Super. 280, 283-84, 645 A.2d 1269 (App. Div. 1994)). AbbVie correctly points out, however, that the Supreme Court rejected a similar risk-utility approach under New Hampshire law—which also held that "a product is defective if the magnitude of the danger outweighs the utility of the product"—because it amounted to a "'stop-selling' rationale" that was "incompatible with [the Supreme Court]'s pre-emption jurisprudence." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 483, 488 (2013) (internal citation and quotation marks omitted). Loreto therefore cannot rely on *Truchan* and the risk-utility analysis to support his negligent design defect claim. The Court grants AbbVie's motion for summary judgment on this

point.[4]

C. Other claims

1. Negligence, implied warranty, unjust enrichment, fraud negligent misrepresentation, consumer protection

The parties agree that Loreto's negligence, implied warranty, and unjust enrichment claims are barred by the New Jersey Product Liability Act (PLA), but they dispute whether the statute also subsumes his fraud, negligent misrepresentation, and consumer protection claims. Loreto argues that although the Court held in a prior case management order that the PLA barred all of the above claims, *In re Testosterone Replacement Therapy Products Liability Litig.*, No. 14 C 1748, 2018 WL 4030586, at *5 (N.D Ill. Aug. 23, 2018) (CMO 132), that order did not address AbbVie's off-label promotion of AndroGel specifically and the condition "low testosterone" more generally.

Yet even if Loreto's claims involve advertising by AbbVie that went beyond AndroGel itself, it is still true that "AbbVie's advertising cannot have caused [the plaintiff]'s injury unless AndroGel did." CMO 132, 2018 WL 4030586, at *5. Loreto alleges that he suffered a heart attack because he took AndroGel while he or his prescribing physicians were unaware of its cardiovascular risks. Unlike the plaintiff in *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602 (E.D. Pa. 2008), Loreto is alleging both that AndroGel was "not reasonably fit for its intended use because it failed to contain adequate warnings or instructions" and that AndroGel itself caused his injury. *Id.* at 618. Consequently, the Court follows CMO 132 and holds that all of Loreto's

[4] As discussed below, the parties agree that Loreto's negligence claim is subsumed by the New Jersey Product Liability Act. *See* section C.1, *infra*. Loreto's design defect claim can therefore only be based on strict liability.

claims are barred by the PLA except "failure to warn; design defect; breach of express warranty; and loss of consortium." CMO 132, 2018 WL 4030586, at *5.

2. Punitive damages

Next is the question of the availability of punitive damages, which turns on which state's law governs that point. The parties agree that New Jersey's "governmental-interest" choice of law analysis applies, but Loreto contends that Illinois law regarding punitive damages should apply under that analysis. Yet in a case involving a Michigan plaintiff suing a New Jersey drug manufacturer, the New Jersey Supreme Court determined that Michigan law applied under the governmental-interest analysis because "[t]o allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state's law and obtain compensation for his injuries in this State's courts completely undercuts Michigan's interests" and "where the . . . challenged drug was approved by the FDA and suit was brought by an out-of-state plaintiff who has no cause of action in his home state, this State's interest in ensuring that our corporations are deterred from producing unsafe products . . . is not paramount." *Rowe v. Hoffman-La Roche, Inc.*, 189 N.J. 615, 629, 917 A.2d 767, 776 (2007). Loreto is in the same position as the plaintiff in *Rowe*. Specifically, he is a lifelong New Jersey resident who took AndroGel in New Jersey and is suing an Illinois corporation. The Court therefore applies New Jersey law regarding punitive damages because under *Rowe* New Jersey has a stronger governmental interest than Illinois.

AbbVie is correct that punitive damages are unavailable under New Jersey law. The PLA "bar[s] punitive damages if the drug has received FDA approval, but grant[s]

an exception 'where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question.'" *McDarby*, 401 N.J. Super. at 91–92, 949 A.2d at 274 (quoting N.J. Stat. Ann. § 2A:58C–5c). The Appellate Division has expressly held, however, that "[b]ecause the punitive damages provisions of [the PLA] impinge upon federal statute and regulation . . . . [w]e thus find [the plaintiff]'s punitive damage claim to have been preempted and reverse that award." *McDarby*, 401 N.J. Super. at 94, 949 A.2d at 276. Loreto cites to only one case, *In re Accutane Litigation*, 235 N.J. 229, 194 A.3d 503 (2018), that discusses *McDarby* in other contexts but does not contradict its holding that the punitive damages exception provision is preempted. The Court concludes that *McDarby* governs here and therefore grants summary judgment in favor of AbbVie on the question of availability of punitive damages.

D. Experts

Federal Rule of Evidence 702 governs admissibility of expert testimony, and the district court acts as a gatekeeper in determining whether proposed expert testimony meets Rule 702's standards. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). The district court's gatekeeping role involves three determinations: (1) whether the expert witness is qualified, (2) whether the expert's methodology is scientifically reliable, and (3) whether the testimony will assist the trier of fact to understand the evidence or determine a fact in issue. *See Myers v. Ill. Central R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010).

1. Dr. Sharlin

AbbVie moves to exclude Dr. Sharlin's report, arguing that he did not review all of

the published studies on the cardiovascular risks of TRT. AbbVie concedes that the Court has admitted a similar opinion from another doctor because "[i]t was appropriate for [that doctor], in offering these opinions, to rely on the testimony of plaintiffs' causation experts regarding what the studies showed and the risks posed by TRT." *In re Testosterone Replacement Therapy Products Liability Litig.*, No. 14 C 1748, 2017 WL 1836443, at *14 (N.D Ill. May 8, 2017). AbbVie argues that this case is different, however, because Dr. Sharlin did not expressly state during his deposition that he relied on Dr. Ardehali's opinion about when the published studies suggested a link between TRTs and cardiovascular injuries, but instead testified that he will rely on Dr. Ardehali's conclusions as to Loreto's case specifically. Yet Dr. Sharlin (1) answered "no" when he was asked if he was going to testify regarding medical causation, (2) stated that he had "the conclusions about what condition [Loreto and other individual plaintiffs] had from Dr. Ardehali," and "based on Dr. Ardehali's medical conclusions, then I can make a regulatory conclusion." Pls.' Opp. to Mot. for Summ. J., Ex J, Sharlin Dep. Tr. ("Sharlin Dep.") at 49:21–24, 49:5–6; 47:22–24. AbbVie seems to argue that Dr. Sharlin will only rely on Dr. Ardehali's analysis for the plaintiffs' individual medical condition and nothing else, but given that Dr. Sharlin repeatedly testified that he would rely on Dr. Ardehali to prove "causation" the Court sees no basis to interpret Dr. Sharlin's statements in such a narrow manner and exclude his testimony on this basis.

AbbVie also contends that Dr. Sharlin's analysis of the adverse event reports in in the FDA's Adverse Event Reporting System (FAERS) is not reliable. Dr. Sharlin analyzed the adverse event reports to conclude that AbbVie did not investigate all the relevant data, as it considered adverse events related to AndroGel but not those related

to other TRT products. AbbVie responds that Dr. Sharlin's analysis is inaccurate and not verifiable, pointing to Dr. Sharlin's testimony that (1) he did not check the data he used for duplicates even though he was aware that FAERS can contain duplicate data, and (2) he could have listed the ID numbers of the adverse event reports he examined so AbbVie could recreate his analysis but did not do so.

Yet both these alleged errors concern the verifiability of Dr. Sharlin's data rather than his methodology, and "[r]eliability . . . is primarily a question of the validity of the methodology employed by an expert, not the quality of the data used in applying the methodology or the conclusions produced." *Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013). Courts are not to "unduly scrutinize[] the quality of the expert's data and conclusions rather than the reliability of the methodology the expert employed," and when there is "a rational connection between the data and the opinion—as there was here—*an expert's reliance on faulty information is a matter to be explored on cross-examination*; it does not go to admissibility." *Id.* at 806, 809 (emphasis added). Even if Dr. Sharlin's data is inaccurate or difficult to confirm, there is a rational connection between the adverse events data and Dr. Sharlin's conclusion that AbbVie did not sufficiently investigate the adverse events suggesting there were cardiovascular risks to AndroGel. AbbVie's concerns with Dr. Sharlin's data thus go to the weight of his testimony rather than its admissibility. The Court declines to exclude Dr. Sharlin's testimony regarding his adverse event report analysis.

2. Dr. Ardehali

AbbVie argues that the Court should exclude Dr. Ardehali's three supplemental reports because Loreto did not serve them until August 17, 2022, about five months

after the March 25, 2022 deadline and one day before Dr. Ardehali's deposition. "Rule 37(c)(1) states that expert testimony may not be presented at trial if the expert's report was not disclosed to the other side within the deadline unless the party was justified in missing the deadline or the untimeliness of the disclosure was harmless." *Dura Auto. Sys. of Ind. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002)

The Court finds that the delay was not justified. Loreto argues that the March 25 deadline for supplemental expert reports was expressly or impliedly understood to be stayed, but in a status report after that deadline, the parties expressly requested an extension of the discovery deadline from April 30 to May 20. There was no indication by the Court (or, for that matter, by the parties in the report) that the supplemental expert report deadline had been stayed, and Loreto did not request a further extension after failing to submit his reports in question by May 20. Loreto also contends that Dr. Ardehali's supplemental reports depended on the data AbbVie produced on May 4, 2022, but he cites to nothing in the record that supports this assertion (nor would this have prevented submission of a report by May 20). As a result, the Court concludes that Loreto's nearly five-month delay in producing Dr. Ardehali's supplemental reports was not justified.

The delay was also not harmless. Of Dr. Ardehali's three supplemental reports, one explained his conclusions after reviewing Loreto's updated medical records. It is undisputed that AbbVie first received this report the day before Dr. Ardehali's deposition, and thus the delay cannot be harmless because it prejudiced AbbVie's ability to prepare for the deposition. Loreto argues that the delay in serving the other two reports was harmless because they were served on AbbVie in other litigation in

New Mexico, but as AbbVie points out, it had no reason to believe that the information in those reports would be introduced in this litigation. Even if the delay in serving those two reports may have been less harmful than the delay of the Loreto-specific report, the Court cannot conclude that serving them less than twenty-four hours before Dr. Ardehali's deposition was harmless.

The Court therefore excludes testimony by Dr. Ardehali related to the contents of his supplemental reports. Dr. Ardehali may, however, testify about the contents of his October 2016 general report and his February 2021 case-specific report regarding Loreto.

Conclusion

For the foregoing reasons, the Court grants AbbVie's motion for summary judgment [dkt. no. 37] on Loreto's negligence, implied warranty, fraud, negligent misrepresentation, unjust enrichment, consumer protection, and punitive damages claims. The Court denies AbbVie's motion on Loreto's other claims, including his strict liability and breach of express warranty claims and Patricia Loreto's loss of consortium claim. The Court also grants AbbVie's motion to exclude Dr. Ardehali's testimony as it relates to his supplemental reports but denies AbbVie's motion to exclude Dr. Sharlin's testimony.

MATTHEW F. KENNELLY
United States District Judge

Date: February 7, 2023